RESPIRATORY MASK

RELATED APPLICATION

[001] This application is a continuation-in-part of Application No. 10/041,523, entitled "SIZE-ADJUSTABLE RESPIRATORY MASK" and filed January 8, 2002, the entire contents of which are hereby incorporated by reference.

FIELD OF THE INVENTION

[002] The present invention relates to respiratory masks used to administer treating gases or medications to patients. A representative treating gas is oxygen, and a representative medication is an aerosol for asthma treatment.

BACKGROUND OF THE INVENTION

[003] Hospitals and respiratory therapists administer treating gases to individual patients by placing a respiratory mask over the patient's nose and mouth. The masks are supplied in standard sizes intended for adults and children. However, many adult patients have smaller facial dimensions such that the standard sizes do not fit properly, at best making the mask uncomfortable and at worst leading to ineffective administration of treating gases. In addition, many children have smaller facial dimensions such that the standard mask sizes provided for children do not fit them. Hence, an adjustable-size respiratory mask is needed to fit patients with smaller facial dimensions.

[004] U.S. Patent 4,657,010 discloses an adjustable face mask in which the bottom of the mask may be extended lengthwise by fastening a separate extension portion (lower portion 14) to the mask. The lower portion 14 is provided with snap closures 42 that mate with eyelet holes 40 in the upper portion of the mask. The separate extension portion is awkward, and size adjustments cannot effectively be made while the mask is in place over a

patient's face. Most patient discomfort is caused when a too large size mask covers their eyes and/or forehead, making the bottom portion size adjustment in this prior patent less helpful when trying to solve the problems associated with over-sized respiratory masks. Moreover, the separate extension portion is more apt to be disconnected or lost before or during use.

SUMMARY OF THE INVENTION

[005] A size-adjustable respiratory mask has a plurality of accordion folds formed between upper portion and a lower portion of the mask. The accordion folds have an open position which is most suited when the mask is to be used for an average or larger size adult, and a folded position most suited for when the mask is to be used for a smaller person. An adjustment member is used to adjust the length of the mask by folding the accordion folds.

[006] The accordion fold may be formed by one or more ribs connected by a flexible material, or by one or more tubes connected by a flexible material. In the most preferred embodiment, the accordion fold is formed integrally with the lower portion of the mask. The entire mask can be formed of a single piece of plastic material of constant thickness.

[007] The mask may be constructed from one or more resilient plastic materials that are known as suitable for medical applications. Preferably, the mask material is latex free and free of other known allergens. Preferably, the mask is constructed from one or more of the following materials: thermoplastic resins, polyurethane resins, poly(vinyl chloride), polypropylene, polyethylene, polystyrene, SURLYN® from E.I. DuPont de Nemours & Company, Inc., or other plastics. A particularly preferred poly(vinyl chloride) is VM 1775 NT Clear 0001 from Maclin Company of City of Industry, California.

DESCRIPTION OF THE FIGURES

[008] **FIG. 1** is a side elevational view of a respiratory mask according to a first embodiment of the invention as sized for an average adult patient;

[009] **FIG. 2** is a fragmental front elevational view of the respiratory mask of FIG. 1;

[0010] **FIG. 3** is a side elevational view of a respiratory mask according to the invention as adjusted in size for a smaller adult patient;

[0011] **FIG. 4** is a fragmental front elevational view of the respiratory mask of FIG. 3;

[0012] **FIG. 5** is a cross-sectional view taken along line 5-5 of FIG. 2 showing size-adjusting means as a button held within an opening in a strap;

[0013] **FIG. 6** is a side elevational view of a respiratory mask according to a second alternate embodiment of the invention;

[0014] **FIG. 7** is a fragmental side elevational view of the respiratory mask of FIG. 6;

[0015] **FIG. 8** is a fragmental partial cross-sectional view showing a ball swivel joint connector engaged within the tubular inlet of a respiratory mask;

[0016] **FIG. 9** is a fragmental side elevational view of a respiratory mask according to a third alternate embodiment of the invention;

[0017] **FIG. 10** is a side elevational view of a respiratory mask according to a fourth alternate embodiment of the invention;

[0018] **FIG. 11** is a front elevational view of a respiratory mask according to a fifth alternate embodiment;

[0019] **FIG. 12** is a side elevational view of the respiratory mask of FIG. 11; and

[0020] **FIG. 13** is an isolated view of an adjustment member of the respiratory mask of FIG. 11.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0021] Referring first to FIG. 1, a respiratory mask **10** includes a mask portion for covering the nose and mouth of a patient receiving a respiratory treatment, such as oxygen or a medicative aerosol or vapor. The mask **10** includes a tubular inlet **12** proximate the nose portion of the mask. A connector **14** is attached to the tubular inlet **12**. A nebulizer (not shown) for delivering the respiratory treatment is in turn attached to the connector **14**. The mask **10** further defines one or more exhaust ports **16,** which are preferred when a mask is used for aerosol or vapor treatments. Head strap brackets **34** are attached to the lateral edges of the mask **10**. One or more elastic head straps (not shown) are threaded through the brackets and wrap around the patient's head to hold the mask in place during treatment.

[0022] The mask **10** is provided with means for adjusting mask size. As shown in FIG. 1, the mask **10** is configured for a normal size adult male. The mask **10** is provided with a deformable metal strap **18** attached by snaps **20.** The metal strap **18** can be bent over the bridge of the patient's nose to help hold the mask in place during treatment.

[0023] Accordion folds **22** are provided in a parallel array at the top of the nose portion of the mask **10**. Each accordion fold comprises a rib or tube of stiffer material than the more resilient plastic material used to form the body of the mask. Each rib or tube is connected by lateral edge to an adjacent rib or tube. When expanded, as shown in FIG. 1, the mask **10** is of a size suitable for an adult male. Preferably, as shown in FIG. 1, the accordion folds **22** are integral with the material forming the top portion of the mask **10.**

[0024] A snap or button **24** is associated with each accordion fold **22**. The buttons **24** are mounted on pins **26** to separate slightly the buttons from the edges of the accordion folds **22**. A band **28** is connected to the deformable metal strap **18** at its proximal end and defines one or more openings **30** at its distal end. The band **28** is formed from poly(vinyl chloride) resin or plastic

material. Preferably, the band **28** has a thickness comparable to the distance of separation between the buttons **24** and the accordion folds **22**. As shown in FIGs. 1, 2 and 5, the uppermost button is held within the most distant hole in the band **28**. It would also be possible to leave the distal portion of the band **28** unattached to any button **24** associated with the accordion folds. In the preferred embodiment, the accordion folds **22** can be expanded to a fully open position such that the mask is suitable for use by a larger adult.

[0025] The means for attaching the band **28** to a button **24** associated with an accordion fold **22** is shown in FIG. 5. The openings **30**, such as eyelet holes, have an inner diameter slightly smaller than the outer diameter of the buttons **24**. Each opening or hole **30** in the band **28** can be snap fit over a button **24**. The snap connection is not permanent, and an adjustment can be made readily by disconnecting the band from a particular button and reattaching to another button.

[0026] Various size adjustments are possible. Referring next to FIGs. 3 and 4, the mask **10** is shown with the accordion folds **22** folded to a closed position to reduce the mask size. In this embodiment, the third opening or hold in the band **28** engages the uppermost button, thus pulling the button and the associated accordion fold **22** tighter toward the deformable strap **18** bridging the nose portion of the mask **10**. With the accordion folds **22** compressed and folded to a closed position, the mask **10** is better suited for use by a smaller adult, such as a woman weighing under 100 pounds, or by a teenager or child.

[0027] Preferably, the mask **10** is fabricated from nonallergenic materials known to be suitable for contacting a patient's skin. Such materials include: thermoplastic resins, polyurethane resins, poly(vinyl chloride), polypropylene, polyethylene, polystyrene, SURLYN® from E.I. DuPont de Nemours & Company, Inc., or other plastics. The preferred mask **10** is formed from a clear poly(vinyl chloride) resin or plastic (with a thickness of about 0.020 inch)

so that a respiratory technician or health care worker can observe the patient's face while treatments are administered. A particularly preferred poly(vinyl chloride) is VM 1775 NT Clear 0001 from Maclin Company of City of Industry, California.

[0028] A second preferred embodiment of the respiratory mask **10** is shown in FIG. 9, wherein the band **28** is provided with a hook strip **84** of a hook and loop fastener (such as a VELCRO® fastener) and the upper surface of the mask is provided with a loop strip **82**. The size of the mask **10** is then adjusted by compressing or folding the accordion folds **22** and causing the hook strip **84** to contact the loop strip **82** to fasten the band **28** to the upper surface of the mask **10** to maintain the accordion folds in a folded position.

[0029] A third preferred embodiment of the respiratory mask **50** is shown in FIGs. 6 and 7. Like parts are numbered with the same reference numerals used in FIGs. 1-5. Rather than using accordion folds **22** (e.g., FIG. 1), the mask **50** incorporates a series of tear strips **36** that have tear tabs **38** at one or both ends. Preferably, the tear strips **36** are integral with the material forming the mask **50** and are separated by grooves **40** or other discontinuities in the thickness of the material. To reduce the size of the mask **50**, one of the tear strips **36** is pulled away from the mask to separate the tear strip **36** and the upper portion of the mask **50** above the strip from the remaining lower portion of the mask.

[0030] As an alternative to the grooves **40**, perforations **42** (FIG. 7) may be provided in the mask material to guide the tearing away of material to reduce the size of the mask **80.**

[0031] The embodiment of the invention shown in FIGs. 1-5 permits variable adjustment of the mask size from larger to smaller. Moreover, once the mask is adjusted to a smaller size, it may still be enlarged to the original adult size or any size therebetween. The embodiments of the invention shown in FIGs. 6 and 7, however, do not provide a means for returning the mask to its

original adult size following the size adjustment made by removing material from the top portion of the mask. Nevertheless, the embodiments of FIGs. 6 and 7 may have fabrication or cost advantages making them suitable for many applications.

[0032] Referring next to FIG. 10, an oxygen mask **90** has small respiration exhaust holes **92** formed in a pattern of concentric rings in each side mask surface. Rather than a connector as shown in earlier mask embodiments, the oxygen mask **90** has a plug **94** attached to the tubular inlet **12**. The plug **94** has a nipple to which is attached a separate tube **96** for introducing oxygen to the patient. A series of angular tapered accordion folds **98** are formed in the mask material above the nose portion, with each fold terminating at pivot point **97**. When the folds **98** are expanded, as shown in FIG. 10, the mask **90** is of a size suitable for an adult male. Preferably, as shown in FIG. 10, the accordion folds **98** are integral with the material forming the top portion of the mask **90**.

[0033] A snap or button **24** is associated with each accordion fold **98**. The buttons **24** are mounted on pins **26** to separate slightly the buttons from the edges of the accordion folds **98**. A band **28** is connected to the deformable metal strap **18** at its proximal end and defines one or more openings **30** at its distal end. The band **28** is formed from poly(vinyl chloride) resin or plastic material. Preferably, the band **28** has a thickness comparable to the distance of separation between the buttons **24** and the accordion folds **22**. As shown in FIG. 10, the uppermost button is held within the most distant hole in the band **28**. It would also be possible to leave the distal portion of the band **28** unattached to any button **24** associated with the accordion folds. In the preferred embodiment, the accordion folds **22** can be expanded to a fully open position such that the mask is suitable for use by a larger adult.

[0034] The size of the mask **90** is reduced to better fit the face of a smaller adult or a teenager or child by creasing or folding the mask material along the

accordion folds **98.** The folds are held in such creased or folded position by inserting one or more of the buttons **24** into holes or openings **30** in the band **28**. Because the folds **98** have a tapered shape that terminates at point **97**, they can be folded to reduce the mask size yet still permit the contours of the outer edges of the mask to better conform to the patient's face.

[0035] Each of the masks **10, 50, 80** and **90** may be modified also by incorporating a swivel joint connection as shown in FIG. 8. The inlet tube **62** has an inner diameter **d1** at its proximal end and an annular groove **64** formed in its distal end. The inlet tube **62** usually is integral with the respiratory mask, and generally depends from a central portion of the mask that is proximate to a patient's nose when the mask is placed on a patient for respiratory treatment.

[0036] A connector **66** is snap fit into the inlet tube **62** during manufacture. The connector **66** has a tubular distal end and a ball joint **68** formed at its proximal end. The ball joint **68** defines an opening **72** such that the connector communicates with the inlet tube to permit gases or treating fluids to flow therethrough. The ball joint **68** is held within the annular groove **64** of the inlet tube **62.** The ball joint **68** defines a center point **70** about which the ball joint may swivel. The center point **70** is positioned within the volume defined by the inlet tube between the uppermost edge of the annular groove and the lowermost edge of the annular groove. With this placement, the connector **66** swivels with respect to the inlet tube **62** so that the distal end of the connector can be moved away from a patient's face when a source tube for a gas treatment or a nebulizer is being connected. In addition, the swivel connection permits the patient to adjust the angle of the source tube for increased comfort.

[0037] A fifth preferred embodiment of a respiratory mask **110** is shown in FIGs. 11-13. In FIGs. 11-13, like parts are numbered with similar reference numerals to those used in FIGs. 1-5, preceded by a "1". The respiratory

mask **110** includes a mask portion for covering the nose and mouth of a patient receiving a respiratory treatment. The mask **110** includes a tubular inlet **112** proximate to an upper or nose portion **113** of the mask **110**. A connector (not shown) may be attached to the tubular inlet **112**. A nebulizer (not shown) for delivering the respiratory treatment is in turn attached to the connector. The mask **110** further defines one or more exhaust ports **116,** which are preferred when the mask **110** is used for aerosol or vapor treatments. Head strap brackets **134** are attached to the lateral edges on either side of the mask **110**. One or more elastic head straps (not shown) may be threaded through the brackets **134** and wrapped around the patient's head to hold the mask **110** in place during treatment.

[0038] As in the embodiment shown in FIGs. 1-5, the mask **110** is provided with a deformable metal strap **118** attached by snaps **120**. The metal strap **118** can be bent over the bridge of the patient's nose to help hold the mask **110** in place during treatment. The metal strap **118** can be made from, for example, aluminum.

[0039] The size of the mask **110** is adjustable by compression or expansion of accordion folds **122** arranged in a parallel array below the upper portion **113** of the mask **110**. An adjustment member **150** is used to adjust the degree to which the accordion folds **122** are compressed. In this way the size of the mask **110** is adjusted along a vertical extent of the mask **110**. When fully expanded, as shown in FIGs. 11 and 12, the mask **110** may be of a size suitable for an adult male. Compressing the accordion folds **122** adjusts the size of the mask **110** to fit smaller persons.

[0040] Each accordion fold **122** may comprise a rib or tube of stiffer material than the more resilient plastic material used to form the body of the mask **110**. In this embodiment, each rib or tube is connected by a lateral edge to an adjacent rib or tube. Preferably, as shown in FIGs. 11 and 12, the accordion folds **122** are integral with the material forming the remainder of the mask

110.

[0041] The accordion folds **122** may also be made as a single continuous piece with and from the same injection-molded material as the remainder of the mask **110**. The entire mask **110** may be formed from, for example, a single thickness of plastic material in order to simplify production. The accordion shape of the folds **122** allows for adjustment of mask size.

[0042] The adjustment member **150** is shown in detail in FIG. 13. Referring to FIGs. 11-13, the adjustment member **150** comprises a first bracket **152** and a second bracket **154** that is movable relative to the first bracket **152**. The relative movement between the first and second brackets **152**, **154** provides adjustment of the size of the mask **110** in the vertical direction.

[0043] The first bracket **152** includes a band portion **153** that is fixedly mounted below the nose portion **113**, and is attached at each end to adjusting bars **158**. The second bracket **154** includes a band portion **155** that is fixedly attached at a bottom portion **130** of the mask **110** below the accordion folds **122**, and includes slots **160** for receiving the adjusting bars **158**. Locking members **162** are pivotably mounted on the second bracket **154**. The locking members **162** have proximal ends that selectively engage teeth **166** on the adjusting bars **158**. The undersides of the teeth **166** slope upwardly so that the bottom portion **130** of the mask **110** can be easily pushed upwardly until a desired tooth **166** is engaged by the proximal end of a locking member, attaining the desired size of the mask **110**. The distal ends of the locking members **162** can be pivoted inwardly (toward the mask as indicated by arrows in FIG. 13) in order to disengage the proximal ends of the locking members **162** from the teeth **166**. The bottom mask portion **130** can then be lowered by extending the accordion members **122**, thereby increasing the length of the mask **110**. Alternatively, the bottom mask portion **130** can be raised, such as in the direction of arrow **A** in FIG. 12 to shorten the length of the mask **110**.

[0044] Referring to FIG. 13, the band portion **155** of bracket **154** is shown in a first open position wherein the accordion folds would be extended or fully open. The band portion **155** is shown in phantom outline in a second more closed position wherein the accordion folds would be partly folded or compressed so that the mask would have a smaller size to fit a smaller sized patient. The locking members **162** are shown with proximal ends engaged to the teeth **166** when in the first open position, and are shown in phantom outline as pivoting inwardly to disengage the proximal ends from the teeth **166** when the band portion is moved upwardly to cause the accordion folds to be partly folded or compressed to reduce the mask size.

[0045] Preferably, the brackets **152**, **154** are attached to the mask at one or more target protrusions or posts **170** extending outwardly from the mask **110**. For example, three posts **170** can extend from the upper portion **113** of the mask **110** to mate with small cavities (not shown) in the band portion **153** and attach the bracket **152**, and three posts **170** can be used to attach the band portion **155** of bracket **154** to bottom mask portion **130**. The posts can be distributed across the width of the upper portion **113** and bottom portion **130** of the mask **110**. The brackets **152**, **154** slide over the posts in a manner similar to the attachment of an aluminum nose clip **118** to snaps **120**. Alternatively, adhesive or glue may be used solely or in combination with protrusions or posts **170** to secure the brackets **152**, **154** to the mask **110**.

[0046] The first and second brackets **152**, **154** can be made as, for example, integral molded plastic parts. Rigid but flexible plastics, such as ABS plastic or polypropylene are preferable.

[0047] The size of the mask **110** may also be adjusted using a button and snap arrangement as illustrated in FIGs. 1-5. A hook and loop fastener arrangement, as illustrated in FIGs. 6-9, or a band arrangement as shown in FIG. 10 may also be used. If any of these arrangements are used in the embodiment of FIGs. 10 and 11, the attachment points for the adjusting

arrangement may be located at the bottom of the mask **110** and below the nose portion **113**.

[0048] The mask **110** may be modified by incorporating a swivel joint connection as shown in FIG. 8.

[0049] The mask **110** illustrated in FIGs. 11-13 includes two exhaust ports **116**, and has the form of an "aerosol" mask. Aerosol masks are used to deliver, for example, medicines to the patient in aerosol form from a nebulizer. The exhausts ports **116** allow the aerosol and gas in the mask **110** to escape.

[0050] In an alternative embodiment (not illustrated), the mask **110** has the form of a "partial rebreather" mask. In this embodiment, the exhaust ports **116** are replaced by a pattern of a plurality of small apertures on each side of the mask **110**, similar to the exhaust holes **92** illustrated in FIG. 10. A reservoir bag, filled with oxygen, is connected to the tubular inlet **112**. An exhalation port is located between the reservoir bag, as part of the bag assembly, and the mask **110**.

[0051] In yet another alternative embodiment (not illustrated), the mask **110** has the form of a "nonrebreather" mask. In this embodiment, the exhaust ports **116** are replaced by a pattern of a plurality of apertures on each side of the mask **110**, similar to the exhaust holes **92** illustrated in FIG. 10. The apertures can be arranged in a circular pattern, with a post in the center each pattern. Each post holds a one-way flap. When a patient inhales, the flaps close against the apertures, preventing outside air from entering the mask **110** through the apertures. The flap pushes away from the apertures when the patient exhales, allowing gases in the mask **110** to escape. An exhalation port is located between the reservoir bag and the mask **110**.

[0052] In yet another alternative embodiment (not illustrated), the mask **110** has the form of a "venturi" mask. The venturi mask has exhaust ports or apertures, similar to the ports **116** shown in FIGs. 11-13, and is connected to a tube at the tubular inlet **112**. A venturi is located in the tube, and

adjustment of airflow through the venturi allows for very precise levels of oxygen to be provided to the patient.

[0053] In still yet another alternative embodiment (not illustrated), the mask **110** has the form of a "simple" mask. The simple mask has a plurality of small apertures on each side of the mask **110**, similar to the exhaust holes **92** illustrated in FIG. 10. In this embodiment, the mask **110** is connected to an adapter at the tubular inlet **112**, which is connected to oxygen tubing.

[0054] Preferably, the mask embodiments disclosed in this specification are fabricated from nonallergenic materials known to be suitable for contacting a patient's skin. Such materials include: thermoplastic resins, polyurethane resins, poly(vinyl chloride), polypropylene, polyethylene, polystyrene, SURLYN® from E.I. DuPont de Nemours & Company, Inc., or other plastics.

[0055] While specific embodiments of the invention have been described and illustrated, such embodiments should be considered illustrative of the invention only and not as limiting the invention as construed in accordance with the accompanying claims.